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NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

UK national guideline for the management of pelvic inflammatory disease 2011.

Bibliographic Source(s)

Clinical Effectiveness Group. UK national guideline for the management of pelvic inflammatory disease 2011. London (UK): British Association for Sexual Health and HIV; 2011 Jun. 18 p. [39 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: United Kingdom national guideline for the management of pelvic inflammatory disease. London (England): British Association for Sexual Health and HIV (BASHH); 2005. 15 p. [34 references]

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 12, 2016 – Fluoroquinolone Antibacterial Drugs : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Definitions of the levels of evidence (I-IV) and grades of recommendation (A-C) are repeated at the end of the "Major Recommendations" field.

What is New in the June 2011 Update?

- The dose of ceftriaxone has been increased to 500mg stat to reflect the reduced sensitivity of *Neisseria gonorrhoeae* to cephalosporins and the current United Kingdom (UK) treatment guidelines for uncomplicated gonorrhoea.

Diagnosis

- Pelvic inflammatory disease (PID) may be symptomatic or asymptomatic. Even when present, clinical symptoms and signs lack sensitivity and specificity (the positive predictive value of a clinical diagnosis is 65% to 90% compared with laparoscopic diagnosis).
- Testing for gonorrhoea and chlamydia in the lower genital tract is recommended since a positive result supports the diagnosis of PID. The absence of infection at this site does not exclude PID however.
- An elevated erythrocyte sedimentation rate (ESR) or C reactive protein also supports the diagnosis but is non-specific.
- The absence of endocervical or vaginal pus cells has a good negative predictive value (95%) for a diagnosis of PID but their presence is non-specific (poor positive predictive value – 17%).

The differential diagnosis of lower abdominal pain in a young woman includes:

- Ectopic pregnancy - pregnancy should be excluded in all women suspected of having PID.
- Acute appendicitis - nausea and vomiting occur in most patients with appendicitis but only 50% of those with PID. Cervical movement pain will occur in about a quarter of women with appendicitis.
- Endometriosis - the relationship between symptoms and the menstrual cycle may be helpful in establishing a diagnosis.
- Complications of an ovarian cyst (e.g., torsion or rupture) often of sudden onset
- Urinary tract infection – often associated with dysuria and/or urinary frequency
- Functional pain - may be associated with longstanding symptoms

Management

It is likely that delaying treatment increases the risk of long-term sequelae such as ectopic pregnancy, infertility and pelvic pain. Because of this, and the lack of definitive diagnostic criteria, a low threshold for empirical treatment of PID is recommended. Broad spectrum antibiotic therapy is required to cover *N. gonorrhoeae*, *C. trachomatis*, and a variety of aerobic and anaerobic bacteria commonly isolated from the upper genital tract in women with PID.

Some of the best evidence for the effectiveness of antibiotic treatment in preventing the long term complications of PID comes from the PEACH study where women were treated with cefoxitin followed by doxycycline – pregnancy rates after 3 years were similar or higher than those in the general population.

The choice of an appropriate treatment regimen may be influenced by:

- Robust evidence on local antimicrobial sensitivity patterns
- Robust evidence on the local epidemiology of specific infections in this setting
- Cost
- Patient preference and compliance
- Severity of disease

General Advice

- Rest is advised for those with severe disease (Grade C [IV]).
- Appropriate analgesia should be provided (Grade C [IV]).
- Intravenous therapy is recommended for patients with more severe clinical disease (Grade C [IV]) (e.g., pyrexia >38ºC, clinical signs of tubo-ovarian abscess, signs of pelvic peritonitis)
- Patients should be advised to avoid unprotected intercourse until they and their partner(s) have completed treatment and follow up (Grade C [IV]).
    - A detailed explanation of their condition with particular emphasis on the long term implications for the health of themselves and their partner(s) should be provided, reinforced with clear and accurate written information (Grade C [IV]).
- When giving information to patients, the clinician should consider the following:
    - An explanation of what treatment is being given and its possible adverse effects
    - Following treatment fertility is usually maintained but there remains a risk of future infertility, chronic pelvic pain or ectopic pregnancy.
    - Clinically more severe disease is associated with a greater risk of sequelae.

- Repeat episodes of PID are associated with an exponential increase in the risk of infertility.
- The earlier treatment is given the lower the risk of future fertility problems.
- Future use of barrier contraception will significantly reduce the risk of PID.
- The need to screen her sexual contacts for infection to prevent her becoming reinfected

Outpatient therapy is as effective as inpatient treatment for patients with clinically mild to moderate PID. Admission for parenteral therapy, observation, further investigation and/or possible surgical intervention should be considered in the following situations:

- A surgical emergency cannot be excluded
- Lack of response to oral therapy
- Clinically severe disease
- Presence of a tubo-ovarian abscess
- Intolerance to oral therapy
- Pregnancy

Further Investigation

All sexually active patients should be offered:

- A pregnancy test
- Screening for sexually transmitted infections including human immunodeficiency virus (HIV)

Treatment

The following antibiotic regimens are evidence based.

Recommended Regimens

All the recommended regimens are of similar efficacy.

Outpatient Regimens

- Intramuscular ceftriaxone* 500 mg single dose followed by oral doxycycline 100 mg twice daily *plus* metronidazole 400 mg twice daily for 14 days (Grade A [Ib])
  *Clinical trial data support the use of cefoxitin for the treatment of PID but this agent is not easily available in the UK so ceftriaxone, which has a similar spectrum of activity, is recommended.

- Oral ofloxacin 400 mg twice daily *plus* oral metronidazole 400 mg twice daily for 14 days (Grade A [Ib]).

Metronidazole is included in some regimens to improve coverage for anaerobic bacteria. Anaerobes are of relatively greater importance in patients with severe PID and metronidazole may be discontinued in those patients with mild or moderate PID who are unable to tolerate it.

Ofloxacin and moxifloxacin should be avoided in patients who are at high risk of gonococcal PID because of increasing quinolone resistance in the UK (e.g., when the patient's partner has gonorrhoea, in clinically severe disease, following sexual contact abroad). Quinolones should also be avoided as first line empirical treatment for PID in areas where >5% of PID is caused by quinolone resistant *Neisseria gonorrhoeae*.

Levofloxacin is the L isomer of ofloxacin and has the advantage of once daily dosing (500 mg once daily [OD] for 14 days). It may be used as a more convenient alternative to ofloxacin.

Replacing intramuscular ceftriaxone with an oral cephalosporin (e.g., cefixime) is not recommended because there is no clinical trial evidence to support its use, and tissue levels are likely to be lower which might impact on efficacy. Reports of decreasing susceptibility of *Neisseria gonorrhoeae* to cephalosporins also support the use of parenteral based regimens when gonococcal PID is suspected (to maximise tissue levels and overcome low level resistance).

Alternative Regimens

- Intramuscular ceftriaxone 500 mg immediately, followed by azithromycin 1 g/week for 2 weeks (Grade A [Ib])
  Clinical trial evidence for this regimen is limited but it may be used when the treatments above are not appropriate (e.g. allergy, intolerance).

- Oral moxifloxacin 400 mg once daily for 14 days (Grade A [Ib])
  Three large randomized controlled trials (RCTs) support the efficacy of moxifloxacin for PID but because of evidence of an increased risk

of liver reactions and other serious risks (such as QT interval prolongation), oral moxifloxacin should be used only when it is considered inappropriate to use the other antibacterial agents recommended for PID or when these have failed.

Inpatient Regimens

Intravenous (i.v.) therapy should be continued until 24 hours after clinical improvement and then switched to oral. Intravenous doxycycline is not currently licensed in the UK but is available from IDIS World Medicines (01932 824100).

- Intravenous ceftriaxone 2 g *plus* i.v. doxycycline 100 mg twice daily (oral doxycycline may be used if tolerated) followed by oral doxycycline 100 mg twice daily *plus* oral metronidazole 400 mg twice daily for a total of 14 days (Grade A [Ib])
- Intravenous clindamycin 900 mg 3 times daily *plus* i.v. gentamicin (2 mg/kg loading dose followed by 1.5 mg/kg 3 times daily [a single daily dose of 7 mg/kg may be substituted]) followed by either oral clindamycin 450 mg 4 times daily or oral doxycycline 100 mg twice daily plus oral metronidazole 400 mg twice daily for 14 days (Grade A [Ib])
  Gentamicin levels need to be monitored if this regimen is used.

Alternative Regimens

Clinical trial evidence for the following regimens is more limited but they may be used when the treatments above are not appropriate (e.g., allergy, intolerance):

- Intravenous ofloxacin 400 mg twice daily *plus* i.v. metronidazole 500 mg 3 times daily for 14 days (Grade B [III])
- Intravenous ciprofloxacin 200 mg twice daily *plus* i.v. (or oral) doxycycline 100 mg twice daily *plus* i.v. metronidazole 500 mg 3 times daily for 14 days (Grade B [III])

Allergy

There is no evidence of the superiority of any one of the suggested regimens over the others. Therefore patients known to be allergic to one of the suggested regimens should be treated with an alternative.

Pregnancy and Breastfeeding

- PID in pregnancy is associated with an increase in both maternal and fetal morbidity; therefore, parenteral therapy is advised although none of the suggested evidence based regimens is of proven safety in this situation.
- There are insufficient data from clinical trials to recommend a specific regimen and empirical therapy with agents effective against gonorrhoea, chlamydial and anaerobic infections should be considered, taking into account local antibiotic sensitivity patterns (e.g., intramuscular ceftriaxone plus oral or i.v. erythromycin, with the possible addition of oral or i.v. metronidazole 500 mg 3 times daily in clinically severe disease) (Grade C [IV]).
- The risk of giving any of the recommended antibiotic regimens (listed above for non pregnant women) in very early pregnancy (prior to a pregnancy test becoming positive) is justified by the need to provide effective therapy and the low risk to the foetus.

Surgical Management

- Laparoscopy may help early resolution of the disease by dividing adhesions and draining pelvic abscesses, but ultrasound guided aspiration of pelvic fluid collections is less invasive and may be equally effective.
- It is also possible to perform adhesiolysis in cases of perihepatitis although there is no evidence whether this is superior to only using antibiotic therapy.

Sexual Partners

- Current male partners of women with PID should be contacted and offered health advice and screening for gonorrhoea and chlamydia. Other recent sexual partners may also be offered screening - tracing of contacts within a 6-month period of onset of symptoms is recommended but this time period may be influenced by the sexual history (Grade C [IV]).
- Gonorrhoea or chlamydia diagnosed in the male partner should be treated appropriately and concurrently with the index patient (Grade C [IV]).
- Because many cases of PID are not associated with gonorrhoea or chlamydia, broad spectrum empirical therapy should also be offered to male partners e.g., azithromycin 1 g single dose (Grade C [IV]).
- If screening for gonorrhoea is not available additional specific antibiotics effective against *Neisseria gonorrhoeae* should be offered, e.g., i.m. ceftriaxone 500 mg single dose (see also UK National Guidelines for Gonorrhoea) (Grade C [IV]).
- Partners should be advised to avoid intercourse until they and the index patient have completed the treatment course (Grade C [IV]).

Follow-up

Review at 72 hours is recommended, particularly for those with a moderate or severe clinical presentation, and should show a substantial improvement in clinical symptoms and signs (Grade C [IV]). Failure to do so suggests the need for further investigation, parenteral therapy and/or surgical intervention.

Further review 2-4 weeks (Grade C [IV]) after therapy may be useful to ensure:

- Adequate clinical response to treatment
- Compliance with oral antibiotics
- Screening and treatment of sexual contacts
- Awareness of the significance of PID and its sequelae
- Repeat pregnancy test, if clinically indicated

Repeat testing for gonorrhoea or chlamydia after 2 to 4 weeks is appropriate in those in whom persisting symptoms, antibiotic resistance pattern (gonorrhoea only), compliance with antibiotics and/or tracing of sexual contacts indicate the possibility of persisting or recurrent infection.

Definitions:

Levels of Evidence

Level	Type of Evidence
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one type of well-designed quasi-experimental study
III	Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grades of Recommendation

Grade	Recommendation
A (Evidence levels Ia, Ib)	Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B (Evidence levels IIa, IIb, III)	Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation
C (Evidence level IV)	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pelvic inflammatory disease

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Treatment

Clinical Specialty

Infectious Diseases

Obstetrics and Gynecology

Preventive Medicine

Urology

Intended Users

Physicians

Guideline Objective(s)

To offer recommendations on the diagnostic tests, treatment regimens and health promotion principles needed for the effective management of pelvic inflammatory disease (PID) covering the management of the initial presentation, as well as how to reduce transmission and future infection

Target Population

Primarily women aged 16 years or older presenting to health care professionals working in departments offering level 3* care in sexually transmitted infection (STI) management within the United Kingdom

*The principles of the recommendations should be adopted across all levels – level 1 and 2 providers may need to develop local care pathways where appropriate.

Interventions and Practices Considered

Assessment/Diagnosis

1. Assessment of clinical features
2. Diagnostic procedures
    - Testing for gonorrhea and chlamydia
    - Erythrocyte sedimentation rate or C reactive protein
3. Testing for absence of endocervical or vaginal pus cells
4. Differential diagnosis of lower abdominal pain

Treatment/Management

1. Broad spectrum antibiotic therapy
    - Recommended regimens (outpatient, inpatient)
    - Alternative regimens
2. Surgical management (laparoscopy)
3. Sexual partner notification, evaluation, and treatment
4. Rest and appropriate analgesia
5. Admission to hospital in specific circumstances
6. Avoidance of unprotected intercourse until patient and partner(s) have completed treatment
7. Patient education
8. Follow-up

Major Outcomes Considered

- Sensitivity and specificity of diagnostic instruments
- Long-term sequelae of pelvic inflammatory disease, such as ectopic pregnancy, infertility, and pelvic pain
- Clinical response to treatment
- Patient compliance with treatment

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Five reference sources were used as the basis for the guideline:

1. Medline and EMBASE Search
    - 1987 to January 2010
      The search strategy comprised the following terms in the title or abstract: 'pelvic inflammatory disease', 'adnexitis', 'oophoritis', 'parametritis', 'salpingitis', 'endometritis', 'PID' (excluding 'primary immune deficiency'), or 'adnexal disease'. 10422 citations were identified.

    - 1963 to 1986:
      The search strategy comprised the following terms in the title or abstract: 'pelvic inflammatory disease', 'adnexitis', 'oophoritis', 'parametritis', 'salpingitis' or 'adnexal disease'. The dataset was then limited to Abridged Index Medicus (AIM) journals and human subjects, identifying 2321 citations.

2. 2010 Centers for Disease Control and Sexually Transmitted Diseases (CDC STD)Treatment Guidelines (www.cdc.gov/std/)
3. 2009 Royal College of Obstetrics and Gynaecology (RCOG) Green Top Guidelines -- Management of Acute Pelvic Inflammatory Disease (www.rcog.org.uk)
4. RCOG Working Group on Pelvic Inflammatory Disease (PID) Report 1996
5. Cochrane Collaboration Databases (www.cochrane.org)

Article titles and abstracts were reviewed and, if relevant, the full text article obtained. Priority was given to randomised controlled trial and systematic review evidence.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Level	Type of Evidence
Ia	Evidence obtained from meta-analysis of randomised controlled trials
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IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one type of well-designed quasi-experimental study
III	Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Recommendations were made and graded by the Clinical Effectiveness Group (CEG) of the British Association for Sexual Health and Human Immunodeficiency Virus (BASHH) on the basis of best available evidence.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Grade	Recommendation
A (Evidence levels Ia, Ib)	Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B (Evidence levels IIa, IIb, III)	Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation
C (Evidence level	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.

IV) Grade	Indicates absence of directly applicable studies of good quality
Recommendation	

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Clinical Validation-Pilot Testing

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Piloting and Feedback

The initial draft of the guideline including the patient information leaflet was piloted for validation by the Clinical Effectiveness Group (CEG) of the British Association for Sexual Health and HIV (BASHH) using a sample of United Kingdom (UK) genitourinary medicine clinics. A standardised feedback form was completed by each pilot site and the guideline amended by the CEG editor. The final guideline was then reviewed by the CEG using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument before posting it on the BASHH website for external peer review for a 3 month period. Comments received were collated by the CEG editor and sent to the guideline chair for review and action. The final guideline was approved by the CEG and a review date agreed before publication on the BASHH website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is graded and identified for select recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management and treatment of pelvic inflammatory disease (PID)

Potential Harms

- Three large randomised controlled trials (RCTs) support the efficacy of moxifloxacin for pelvic inflammatory disease (PID) but because of evidence of an increased risk of liver reactions and other serious risks (such as QT interval prolongation), oral moxifloxacin should be used only when it is considered inappropriate to use the other antibacterial agents recommended for PID or when these have failed.
- Allergy or intolerance to medications

Qualifying Statements

Qualifying Statements

- The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and available resources.
- All possible care has been undertaken to ensure the publication of the correct dosage of medication and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Clinical Effectiveness Group. UK national guideline for the management of pelvic inflammatory disease 2011. London (UK): British Association for Sexual Health and HIV; 2011 Jun. 18 p. [39 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Aug (revised 2011 Jun)

Guideline Developer(s)

British Association for Sexual Health and HIV - Medical Specialty Society

Source(s) of Funding

This guideline was commissioned, edited and endorsed by the British Association of Sexual Health and HIV (BASHH) Clinical Effectiveness Group (CEG) without external funding being sought or obtained.

Guideline Committee

Clinical Effectiveness Group (CEG)

Composition of Group That Authored the Guideline

Authors: Prof Jonathan Ross (*Lead author*), Professor of Sexual Health and HIV, Whittall Street Clinic; Dr Gill McCarthy (*Lead editor on behalf of BASHH CEG*), Consultant Physician Sexual Health an HIV, The Wolverton Centre, Kingston Hospital NHS Trust, Kingston upon Thames

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Financial Disclosures/Conflicts of Interest

All members of the guideline writing committee completed the British Association for Sexual Health and HIV (BASHH) conflict of interest declaration detailed below at the time the guideline's final draft was submitted to the Clinical Effectiveness Group (CEG).

Dr. Jonathan Ross has received consultancy fees from Bayer Pharma.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: United Kingdom national guideline for the management of pelvic inflammatory disease. London (England): British Association for Sexual Health and HIV (BASHH); 2005. 15 p. [34 references]

Guideline Availability

Electronic copies: Available from the British Association for Sexual Health and HIV Web site .

Availability of Companion Documents

The following is available:

- British Association for Sexual Health and HIV: framework for guideline development and assessment. British Association for Sexual Health and HIV; 2010. 18 p. Electronic copies: Available in PDF from the BASHH Web site .

In addition, auditable outcomes are provided in the original guideline document .

Patient Resources

The following is available:

- A guide to pelvic inflammatory disease - PID. Patient information leaflet. London (UK): British Association for Sexual Health and HIV; 2012 Jan. 2 p. Available in Portable Document Format (PDF) from the British Association for Sexual Health and HIV (BASHH) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on December 8, 2000. The information was verified by the guideline developer on January 12, 2001. This summary was updated on August 5, 2002, and on November 1, 2005. The updated information was verified by the guideline developer on January 19, 2006. This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs. This summary was updated by ECRI Institute on May 5, 2009, following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This NGC summary was updated by ECRI Institute on June 6, 2012. This summary was updated by ECRI Institute on October 25, 2013 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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